Preliminarily, the Applicants wish to thank the Examiner for the thorough examination of the application and the helpful suggestions for amendments of the claims.

Claims 1-50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The In order to more clearly define the present invention, the Applicants have amended the above claims in accordance with the Examiner's suggestions. By the above amendments, the Applicants assert that the Examiner's rejections have been fully addressed and accordingly, withdrawal of the rejections is respectfully requested.

Claims 1-26 are rejected under 35 U.S.C. § 102(b) as being anticipated by Catt et al. ('778). The Applicants respectfully traverse the rejection.

The present invention as now defined by amended claim 1 is drawn to an electronic monitoring device designed to monitor the ovulation cycle so as to detect ovulation, with a view to use as an aid to conception for couples having difficulty in that regard. As such, the device of claim 1 is fundamentally different from those disclosed in U.S. 5,467,778 (Catt et al.), which are provided as aids to contraception (see, for example, Catt et al., at column 1, lines 6-10 and 46-48; column 2, lines 66-67), and therefore "fail safe". Accordingly, the prior art devices must predict the onset of the unsafe period before the user actually enters the unsafe period. Thus, the indication of the unsafe period in the prior art device commences earlier, and ends later, than the indication of elevated fertility provided by the monitor of the present invention. The disclosure of Catt et al. could not be used successfully to obtain the present invention as now claimed.

The monitoring device in claim 1 provides two signals to a user; a first signal indicating that fertility is elevated (typically generated by detection of a concentration change in E3G; see claim 4)

and a second signal that fertility is maximum, at the time of ovulation (typically generated by detection of a concentration change in LH; see claim 2).

It is implicit in the foregoing that the monitoring device of claim 1 therefore provides at least a semi-quantitative display of information regarding the fertility of the subject. For example, no signal (= non-fertile); first signal (= elevated fertility); and second signal (= maximum fertility).

The Applicants respectfully assert that there is no disclosure in '778 of a device, which provides such a semi-quantitative display of information regarding the fertility of the subject. Since the devices disclosed in the prior art address the problem of providing contraceptive advice, the prior art monitors indicate only whether it is safe or unsafe to have unprotected intercourse. The indication provided by '778 is entirely inadequate to provide the information, which the present invention gives to the user.

Moreover, detection of a concentration change in an analyte, such as LH, which indicates actual ovulation is an essential feature of the present invention. Detection of actual ovulation in the current cycle of the subject is indicated to the user of the monitor as a period of maximum fertility. In contrast, in the prior art LH is generally measured only to determine the day of ovulation in previous cycles, not in the current cycle (see column 5, lines 4-26 and column 7, lines 40-48 of '778), and the reason for measuring LH is to determine an appropriate "E3G testing commencement day" for subsequent cycles. Thus there is no explicit teaching or inherent suggestion in the prior art document that the monitoring device should provide an indication of occurrence of maximum fertility based on measurement of LH concentration.

Moreover, with particular reference to claim 7, there is no teaching in the cited art of a device, which includes a "non-indicating" feature of the type recited in the claim. This is because

the prior art devices are intended to provide contraceptive advice and therefore "fail safe" (see column 11, lines 50-52). Thus a non-indication of maximum fertility, unless both second and first analyte changes are detected, is diametrically opposed to the teaching of the prior art.

Similarly, the details of the display provided by the monitor, as recited in claim 9 of the present application, are not disclosed by the cited art. Moreover since the monitoring devices of the art are primarily concerned solely with providing a "safe/unsafe" answer, there is no motivation for the person skilled in the art to provide a monitoring device having the type of display recited in claim 9, especially since the display of claim 9 indicates "the most appropriate time in the cycle to attempt conception". No contraceptive assistance monitor of the type disclosed in the prior art would indicate this sort of information and the prior art reference completely fails to suggest any modification to obtain that sort of information.

In relation to claim 10, the cited art is completely silent as to provision of the monitor device with an interface means which communicates with electronic data transmission means (such as a smart card or floppy disk - see page 15, last paragraph, of the description of the present application). Indeed, the monitor of the prior art is intended for use as an aid in contraception, so there is no likely reason why such a monitor should be provided with such an interface, the purpose of which is to allow data to be transferred from the monitor to the data transmission means, which (according to the present invention is then typically used to transfer the data to a computer means of a health professional).

Claims 12-16 are directed to a test kit which comprises the monitor of claim 1, hence the foregoing comments equally apply.

Claims 27-50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Catt et al. ('778) in view of Beach et al. The Applicants respectfully traverse the rejection.

As for the rejection under 103, we submit that the combination of cited art does not disclose all the features of the claimed invention and, moreover, is a combination, which is made in hindsight with knowledge of the present invention.

Firstly, the monitor of Catt et al. ('778), is primarily intended as an aid to contraception. The Applicants comments regarding the '778 reference detailed above equally apply to the present rejection. The disclosure of Beach et al. fails to make up for the deficiencies of '778 and furthermore, provides no motivation for the person skilled in the art to obtain data from the monitors and transfer the data to a health professional. Such professional assistance is not required for contraception. Only by modifying '778 without any teaching or suggestion and only by using the Applicants' invention as a template could a combination be made with Beach et al. to attempt to obtain the result of the present invention. Nowhere is there any suggestion in U.S. 5,467,778 that data obtained by and stored in the monitors could (i) be transferred to a health professional or (ii) be used to obtain advice from a health professional concerning conception and certainly, the teaching of Beach et al. does not suggest that the '778 disclosure would be useful toward obtaining the Applicants' invention. Further, there is no suggestion that the data could be transferred to a health professional in electronic form via an interface means communicating with an electronic data transmission means. The "obvious" method (if any) of transferring the data would be to provide the monitor with means for producing a paper print out of the data, as is known in the art of assays in general. No teaching or suggestion for such a modification is provided.

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The monitor disclosed in U.S. 5,881,673 (Beach et al.) is entirely different from that of '778 and that of the present invention. The monitor disclosed by Beach et al. is intended for use with cattle, not humans and as such is even further devoid of any teaching or suggestion to combine with '778 to obtain the present invention.

Further, the monitor disclosed by Beach et al. comprises a crude pressure sensor to determine the frequency with which a cow is mounted. The monitor therefore does not record data relating directly to fertility of the cow and can only provide data, which are an indirect indication of the fertility status of the cow. Further, the monitors of Beach et al. cannot determine the day of ovulation of the cow.

In addition, in Beach et al., the cow-mounted recording unit downloads data to the receiving unit by radio transmission. The recording unit has no interface means, which interacts with a data transmission means. Such an interface is only provided on the receiving unit, which does not equate to the monitor used in the method of claim 26.

The Applicants respectfully assert that even using the Applicants invention as a template, the combination of '778 with Beach et al. fails to obtain the present invention. Further, there is not the slightest teaching or suggestion in either reference to combine the references. This is particularly true of the '778 reference, which is totally directed to contraception. "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)" *See* MPEP 2142.

Having addressed all of the Examiner's objections and rejections, the Applicants respectfully assert that the present application is now in condition for allowance. Early and

favorable notice to that effect is respectfully solicited. If the Examiner believes it would further the progress of the present application to an early allowance date, a telephone call to the undersigned is earnestly invited.

Respectfully submitted,

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